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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/732,843	12/10/2003	Chris Cienas	END-5007NP	6679
27777	7590	04/09/2007	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			NGUYEN, HUONG Q	
			ART UNIT	PAPER NUMBER
			3736	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		04/09/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/732,843

Applicant(s)

CICENAS ET AL.

Examiner

Helen Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. This Office Action is responsive to the amendment filed 1/11/2007. Claims 1-2, 14, and 17-18 are amended. **Claims 1-20** remain pending.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. **Claims 1, 3, 7, and 9-13** are rejected under 35 U.S.C. 102(b) as being anticipated by Gregoire et al (US Pat No. 5944673).

4. In regards to **Claim 1**, Gregoire et al disclose a biopsy device comprising:

a hollow biopsy needle or “piercing needle” (51) having a tissue receiving port (55);

a hollow cutter (60) having a distal end advanceable within the biopsy needle to sever tissue received within the tissue receiving port;

a sample tube or “tissue extractor” (65) advanceable within the hollow cutter when the distal end of the cutter is positioned within the biopsy needle, the sample tube having an open distal end (an opening 70 disposed at the distal end best seen in Figure 2) sized for receiving a tissue sample severed by the hollow cutter (Col.9: 13-17) best seen in Figures 10-11, the sample tube being releasably supported on the biopsy device such that the sample tube and at least one

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tissue sample stored therein may be removed from the biopsy device without disassembling the biopsy device, best seen in Figure 12.

5. In regards **Claim 3**, Gregoire et al disclose a vacuum source (86) in communication with the sample tube (65) (Col.9, line 8-10). In regards to **Claim 7**, Gregoire et al disclose an apparatus for advancing and retracting the cutter within the biopsy needle. Specifically, Gregoire et al disclose a “cutter advance fork” (33) to move the cutter proximally and distally (Col.6, line 56-65).

6. In regards to **Claim 9**, Gregoire et al disclose the hollow needle comprising a lateral tissue receiving port (55) spaced from the distal end of the needle (Figure 2). In regards to **Claim 10**, Gregoire et al disclose the sample tube or tissue extractor comprising a vacuum lumen and a sample lumen. In particular, vacuum lumen is defined as the “extractor channel” (76) and the sample lumen is defined as the “tissue receptacle” (70). In regards to **Claim 11**, Gregoire et al disclose the sample tube comprising a tube wall feature for retaining tissue samples, specifically, a “tissue receptacle” (70).

7. In regards to **Claim 12**, Gregoire et al disclose the tube wall feature comprising a notch or tissue receptacle (70) disposed adjacent the distal end of the sample tube (Col.7, line 4-6). In regards to **Claim 13**, Gregoire et al disclose a rotating journal for rotating and advancing the cutter. The rotating journal is defined as the “driver gear” (34) and “cutter advance knob” (32),

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both of which must rotate to rotate and advance the cutter, respectively (Col.6, line 10-12, 63-65).

8. **Claim 16** is rejected under 35 U.S.C. 102(b) as being anticipated by Burbank et al (US Pat No. 5526822).

9. Burbank et al disclose a biopsy device comprising:

a hollow biopsy needle (44) having a lateral tissue receiving port (46);

a hollow cutter (68) advanceable within the biopsy needle to sever tissue received within the tissue receiving port;

a sample tube or "tubular knock out pin" (92) having an open distal end defining a distal opening defining a generally circular plane transversely intersecting a central axis of said sample tube, a proximal end in communication with a source of vacuum (Col.14, line 47-50), said sample tube releaseably supported on the biopsy device and advanceable within the cutter;

a drive mechanism for advancing and rotating the cutter within the biopsy needle comprising an internally threaded, rotatably driven component for advancing and rotating the cutter including internally threaded "cannular inner cutter collet" (762), "motor" (780), and rotatably driven "drive gear" (776) and "indexing gear" (772), best seen in Figure 17 (Col.19, line 49-67), collectively used for advancing and rotating the cutter.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. **Claim 2** is rejected under 35 U.S.C. 103(a) as being unpatentable over Gregoire et al in view of Chin et al (US Pat No. 5195533).

15. Gregoire et al disclose the device including the sample tube above but disclose the sample tube adapted to store multiple samples in an end to end configuration. Chin et al disclose taking multiple samples in an end to end configuration within the same biopsy needle for ease and efficiency of sampling (Col.2, line 28-34). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to store multiple samples in an end to end configuration, as taught by Chin et al, into the sample tube disclosed by Gregoire et al, to provide a more atraumatic and efficient method of sampling.

12. **Claims 4-6** are rejected under 35 U.S.C. 103(a) as being unpatentable over Gregoire et al in view of Bates et al (US Pat No. 6273861).

13. In regards to **Claim 4**, Gregoire et al disclose a biopsy device comprising of a sample tube or "tissue extractor" (65) but do not disclose a fluid method of advancing the tissue extractor. Bates et al disclose a source of compressed fluid as an advantageous means of advancing a tissue excising means of a tissue sampling device (Col.8, line 27-36). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to advance the sample tube of Gregoire et al using fluid pressure, as taught by Bates et al, to further automate the biopsy device and obtain the benefits associated with using fluid pressure.

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10. In regards to **Claim 5**, Gregoire et al disclose a sample tube or "tissue extractor" (65) but do not disclose a pneumatic means of advancing the tissue extractor. Bates et al disclose a pneumatically operated tissue sampling device to impart the advantages of automating a biopsy device using compressed gas (Col.10, line 32-33). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to advance the sample tube of Gregoire et al pneumatically, as taught by Bates et al, to further automate the biopsy device and obtain the benefits associated with using compressed gas.

11. In regards to **Claim 6**, Gregoire et al disclose a sample tube of "tissue extractor" (65) but do not disclose a piston operatively associated with the tube. Bates et al disclose a stylet piston (290) and cannula piston (307) using compressed fluid to provide the necessary force to automatically drive the sampling device (Col.15, line 43-67). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include a piston, as taught by Bates et al, operatively associated with the sample tube of Gregoire et al, to similarly automate the sample tube of the biopsy device and obtain the associated benefits.

12. **Claim 8** is rejected under 35 U.S.C. 103(a) as being unpatentable over Gregoire et al in view of Burbank et al (US Pat No. 5526822).

14. Gregoire et al disclose a sample tube or "tissue extractor" (65) but do not close an apparatus for advancing and retracting the extractor within the cutter. Burbank et al disclose a "tubular knock out pin linear driver" (112) supplying linear motion to automate the sample tube, referred to as "tubular knock out pin" (92) (Col.14, line 40-41). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include an

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apparatus for advancing and retracting the sample tube of Gregoire et al, as taught by Burbank et al, to fully automate the biopsy device as automation decreases trauma and increases the consistency and quantity of tissue samples (Col.4, line 40-43).

15. **Claims 14-15** are rejected under 35 U.S.C. 103(a) as being unpatentable over Gregoire et al in view of Farascioni (US Pat No. 6019733).

16. Gregoire et al disclose a cutter (60) but do not disclose the cutter having at least one hole extending through an outer surface of the cutter and spaced from a distal end, the at least one hole positioned for providing vacuum axially through the cutter when at least one tissue sample is disposed within the sample tube within the cutter. However, Gregoire et al do disclose vacuum through the cutter, wherein vacuum (86) is used through the sample tube (65), which is inserted into the cutter. Farascioni teach a plurality of holes (32) spaced from the distal end extending through an outer surface of one component of an analogous biopsy device to effectively allow vacuum axially therethrough for proper sampling, best seen in Figure 2. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the cutter of Gregoire et al to include a plurality of holes extending through an outer surface and spaced from the distal end for providing vacuum axially, as taught by Farascioni, such that vacuum is supplied when at least one tissue sample is disposed within the sample tube within the cutter, to allow more effective sampling by providing an adequate suction mechanism.

17. **Claims 17-20** are rejected under 35 U.S.C. 103(a) as being unpatentable over Burbank et al in view of Banik et al (US Pat No. 6053877).

18. In regards to **Claim 17**, Burbank et al disclose a method of obtaining a tissue sample comprising the steps of:

drawing tissue into a tissue receiving port (46) of a hollow biopsy needle (44);

advancing a hollow cutter (68) in the needle to sever a tissue sample;

a sampling mechanism comprising a hollow sample tube (92) (Col.17: 48-51).

However Burbank et al do not disclose the sampling method comprising the step of advancing the hollow sample tube in the cutter to position the tissue sample in the sample tube, wherein the tissue sample is axially received in the hollow sample tube through an open distal end during the act of advancing the hollow sample tube, and then removing the sample tube from the hollow cutter with at least one tissue sample positioned within the sample tube.

19. Banik et al disclose an effective sampling mechanism comprising a hollow sample tube (20) with an open distal end, wherein the hollow sample tube is advanced in a hollow cutter (14) to position a tissue sample in the sample tube, wherein the tissue sample is axially received in the hollow sample tube through an open distal end during the act of advancing the hollow sample tube (Col.6: 37-48), and then removing the sample tube from the hollow cutter with at least one tissue sample positioned within the sample tube (Col.10: 3-17), as an effective sampling mechanism that allows collection of multiple samples at one time, best seen in Figures 2 and 5D.

20. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to replace the sampling mechanism of Burbank et al with the sampling mechanism of Banik et al such that a hollow sample tube is advanced in the cutter with the distal end of the hollow cutter disposed in the needle, to position the tissue sample in the sample tube, the tissue sample is axially received in the hollow sample tube through an open distal end during

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the act of advancing the hollow sample tube, and then removing the sample tube from the hollow cutter with at least one tissue sample positioned within the sample tube, as an equally effective sampling mechanism that also advantageously allows the simultaneous collection of multiple samples.

10. In regards to **Claim 18**, Banik et al disclose stacking multiple samples in an end to end configuration within the sample tube, best seen in Figure 5D.

11. In regards to **Claim 19**, Burbank et al disclose a method comprising providing a vacuum through the sample tube (578) (Col.15, line 6-8).

21. In regards to **Claim 20**, Burbank et al in combination with Bank et al disclose a method comprising providing axial vacuum in the cutter through the sample tube with at least one sample disposed the sample tube for the reasons elaborated above.

Response to Arguments

22. Applicant's arguments filed 1/11/2007 regarding **Claim 16** have been fully considered but they are not persuasive. Applicant contends that the knock out pin (92) is not a sample tube and that the embodiment described in column 17 lines 24-51 where the knock out pin (292) can have an open end does not correspond to the invention of applicant. However, the Examiner notes that in column 17 lines 48-51, Burbank et al disclose that "in other embodiments, the end of the knock out pin is open" which properly teaches that other embodiments, including the one

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at hand, allow for the knock out pin to be open and thus constitute a sample tube, such as the embodiment shown by knock out pin (92). Furthermore, Burbank et al disclose the sample tube (92) releasably supported on the biopsy device, which is interpreted to mean that said sample tube is capable of being disconnected from the biopsy device, as required by the claim recitation of "releasably."

23. Applicant also contends that Burbank et al do not disclose a drive mechanism comprising an internally threaded, rotatably driven component. The Examiner notes that Burbank et al disclose motor (780) and rotatably driven gears (772,776), best seen in Figure 17, as well as internally threaded collet (762), wherein said components collectively comprise the drive mechanism comprising an internally threaded, rotatably driven component for advancing and rotating the cutter, as explained in the rejection above (Col.19: 49-67).

24. Applicant's arguments with respect to **Claims 1-15 and 17-20** have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

25. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen Nguyen whose telephone number is 571-272-8340. The examiner can normally be reached on Monday - Friday, 8 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

HQN
3/28/2007



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